

GAU-1816 \$

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HEW52:WP51  
DEB:HEW:AJC:lbj  
12/30/97



PATENT APPLICATION  
DOCKET NO.: LKS95-10

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Paul D. Ponath, Douglas J. Ringler, S. Tarran Jones,  
Walter Newman, José Saldanha and Mary M. Bendig

Application No.: 08/700,737

Group Art Unit: 1816

Filed: August 15, 1996

Examiner: E. Rabin

Title: HUMANIZED IMMUNOGLOBULIN REACTIVE WITH  $\alpha 4\beta 7$  INTEGRIN

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Honorable Commissioner of Patents and Trademarks, Washington D.C. 20231	
on 12/30/97	<i>Lisa Jensen</i>
Date	Signature
Lisa Jensen	
Typed or printed name of person signing certificate	

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**GROUP 180**

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)

☐ under 37 CFR 1.97(b), or  
(Within three months of filing national application; or date of entry of the national stage in international application; or before mailing date of first office action on the merits; whichever occurs last)

☒ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☒ a \$240.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

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☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a Petition under 37 CFR 1.97(d)(2), and

☐ a \$130.00 petition fee set forth in 37 CFR 1.17(i).

(Filed after final action or notice of allowance, whichever occurs first, but before payment of the issue fee)

☐ Applicant requests that the attached IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

☐ Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or

☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Enclosed herewith is form PTO-1449:

☒ Copy of the cited reference AF is enclosed.

☐ Copies of cited references are enclosed except those entered in prior application, U.S. Serial No. \_\_\_\_\_, and references that are not required to be submitted under 37 CFR 1.98.

☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.

Concise Explanation Requirement (non-English references):

☐ The "concise explanation" requirement for reference(s) \_\_\_\_\_ under 37 CFR 1.98(a)(3) is satisfied by:

☐ the explanation provided on the attached sheet.

☐ the explanation provided in the Specification.

[ ] submission of the enclosed International Search Report.

[ ] the enclosed English language abstract.

Method of payment:

[X] Enclosed is a check in the amount of \$240.00.

[ ] Please charge Deposit Account 08-0380 in the amount of \$\_\_\_\_\_.

[X] A copy of this Statement is enclosed.

[X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

REMARKS

Subsequent to filing the subject application, Applicants learned that the Fc region used to construct an Fc-mutated variant of a humanized Act-1 antibody actually contains a Leu → Ala mutation at position 235 of the constant region, rather than at position 234 (Specification, at page 90, line 3). This mutation is also present in a control anti-CD18 antibody (Specification, at page 90, line 13 and at page 108, line 16) and in a MADCAM-IgG chimera (Specification, at page 114, line 2 and line 9) which were used in various studies described in the exemplification. In each case, the Fc region mutations were from Leu<sup>235</sup> → Ala<sup>235</sup> and Gly<sup>237</sup> → Ala<sup>237</sup>.

It is requested that the information disclosed herein be made of record in this application.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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